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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/080,130	02/19/2002	Romano Deghenghi	87264-300	9172

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EXAMINER	
DI NOLA BARON, LILIANA	

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 12/30/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/080,130	DEGHENGHI ET AL.	
	Examiner	Art Unit	
	Liliana Di Nola-Baron	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 February 2002*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *19 February 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 26-28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

3. Claim 26 recites the limitation "A lyophilized composition comprising the dried suspension of claim 12" in lines 1-2. There is insufficient antecedent basis for this limitation in the claim, since claim 12 reads on an aqueous suspension.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claim 30 is rejected under 35 U.S.C. 102(e) as being anticipated by Gunther et al. (U.S. Patent 6,258,933).

The patent discloses Antarelix trifluoroacetate and its amino acid sequence, which is the trifluoroacetate salt of the peptide claimed by Applicant (See Example 4).

The peptide salt disclosed by Gunther et al. meets the limitations of claim 30 of the instant application, thus the patent anticipates the claimed invention.

6. Claims 1-6, 9-17, 20-24, 26-29 and 31 are rejected under 35 U.S.C. 102(e) as being anticipated by Damm et al. (U.S. Patent Application Publication 2002/0198146).

Damm et al. provides a method of synthesizing peptide salts. With regard to claims1, 2, 12 and 13, the method disclosed by Damm et al. comprises adding acids, including benzenesulfonate and sulfate, to a peptide to form the corresponding salts in a cloudy suspension (See p. 1, 0017 to p. 2, 0023).

Regarding claims 3-6 and 14-17, Damm et al. teaches that preferred peptides are LHRH antagonists (also known as GnRH antagonists), and includes antarelix (having the sequence claimed in claims 5 and 16 of the instant application), abarelix, azaline and cetrorelix among the peptides used in the method of the invention (See p. 1, 0005).

With regard to claims 9 and 20, Damm et al. teaches that the suspension of the peptide salt in water is filled in amounts of 3.0 g into 10 ml injection flasks (See p. 2, 0022), thus the concentration of the peptide salt in the aqueous suspension is 300 mg/ml.

With respect to claim 10, Damm et al. teaches that an aqueous suspension of the peptide salt is administered parenterally, and the effect can be 2-8 weeks or longer (See p. 2, 0027-0028).

Regarding claims 11 and 24, Damm teaches that a dose of 30-150 mg is administered (See p. 2, 0028). If a person weights 50 kg, the dose disclosed by the prior art corresponds to a dose range of 06-3 mg/ kg body weight, which is in the range claimed by Applicant.

With regard to claims 21-23, Damm et al. teaches that adjuvants can be added to the composition before or after filtration, and includes mannitol among said adjuvants (See p. 1, 0015-0016).

With regard to claims 26-29, , Damm et al. teaches removing the diluent in the method of the invention (See claim 1). Specifically, Damm et al. discloses a lyophilizate of centrolix embonate, which is resuspended in water and administered parenterally (See p. 2, 0027).

With respect to claim 31, Damm et al. includes antarelix, which is a peptide having the sequence claimed in claim 31 of the instant application, among the peptides used in the method of the invention to form salts with acids including sulfate (See p. 1, 0005 and 0017).

The method and compositions disclosed by Damm et al. meet the limitations of claims 1-6, 9-17, 20-24, 26-29 and 31 of the instant application, as the patent application publication contemplates combining a peptide with an acid to form suspension of the corresponding salts, drying the

obtained compositions and resuspending the salts in water for administration to patients. Thus, Damm et al. anticipates the claimed invention.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claims 7, 8, 18, 19 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Damm et al. as applied to claims 1-6, 9-17, 20-24, 26-29 and 31 above, and further in view of Gander et al. U.S. Patent 5,648,096).

The teachings of Damm et al. have been summarized above. With regard to claims 7, 8, 18 and 19, the patent application publication is deficient in the sense that it does not include somatostatin analogues among the peptides used in the invention. With respect to claim 25, Damm et al. is deficient in the fact that it does not disclose the particle size in the suspensions of the invention.

Gander et al. provides suspensions of active agents in a micronized form and teaches that the particles are smaller than 10 microns (See col. 4, lines 41-51). Gander et al. includes antide, somatostatin and analogs, octeotride, lanreotide and vapreotide, among the LHRH analogs used as active agents in the invention (See col. 7, lines 41-45).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to include somatostatin analogs in the method and suspensions disclosed by Damm et al. to obtain compositions having a wider medical effect. The expected result would have been a successful method of producing peptide compositions for injection. Because of the teachings of Damm et al., that stable peptide salts may be obtained by the method of the invention, and the teachings of Gander et al., that somatostatin analogs and LHRH antagonists are LHRH analogs and may be equally suspended in micronized form in particles smaller than 10 microns, one of ordinary skill in the art would have a reasonable expectation that the method and compositions claimed in the instant application would be successful in producing therapeutic injectable compositions. Therefore the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Liliana Di Nola-Baron whose telephone number is 703-308-8318. The examiner can normally be reached on Monday through Thursday, 5:30AM-4:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on 703-308-2927. The fax phone number for the organization where this application or proceeding is assigned is 703-305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 308-1234/ 1235.

LDN 03

December 23, 2003

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600